IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION

FEDERAL TRADE COMMISSION,	)	
	)	
Plaintiff,	)	**Case No. 15-cv-01080-DAP**
	)	
v.	)	**JUDGE DAN AARON POLSTER**
	)	
STERIS CORPORATION,	)	**FILED UNDER SEAL**
	)	
and	)	
	)	
SYNERGY HEALTH plc,	)	
	)	
Defendants.	)	

PLAINTIFF FEDERAL TRADE COMMISSION'S
POST-HEARING RESPONSE BRIEF

INTRODUCTION

The crux of Defendants' argument is that the preliminary injunction should not issue because the Federal Trade Commission cannot prove that Synergy's x-ray strategy "would have overcome the substantial obstacles to corporate approval within any reasonable time."[1] But the evidentiary support for Defendants' key assertions—that financial hurdles doomed the project, and that top corporate officials who approved the strategy at the SEB and down payments at the plc Board would have done an about-face at some unspecified time in the future—consists solely of the testimony of Synergy officials that is contradicted by contemporaneous evidence.

The real-time words and deeds of the high-level Synergy decision-makers, embodied in numerous ordinary course documents, are consistent and clear: Synergy expected to enter the United States with x-ray, a disruptive and transformative move designed to differentiate the company from Steris and Sterigenics so that Synergy could become the number one global sterilizer. Synergy's board reports, presentations, and minutes; communications among senior executives; and actions taken by the company—i.e., the best evidence to demonstrate a firm's commitment to enter a market—demonstrate that Synergy likely would have entered the United States with x-ray absent the proposed transaction.[2] Defendants would have this Court disregard the wealth of highly probative, ordinary course evidence. But the self-serving, post-transaction testimony of Synergy's executives is precisely the kind of evidence that courts in antitrust cases view with skepticism and afford little weight.[3] This Court should do the same, and grant the FTC's motion for a preliminary injunction.

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[1] Defendants' Post-Hearing Brief on Synergy Non-Entry, Doc. No. 79 ("Defs.' Br."), at 1.

[2] As the FTC noted in *B.A.T Indus.*, "[t]he best evidence concerning the incentives of the [alleged potential entrant] . . . is likely to be subjective" and would answer the questions "how did the firm evaluate its independent entry prospects? Did it find them to be sufficiently attractive to warrant preparing concrete capital investment plans? Did its corporate management approve those plans?" *In re B.A.T. Indus., Ltd.*, 104 F.T.C. 852, 927 (1984).

[3] *See, e.g.*, *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 435 (5th Cir. 2008) ("The probative value of [post-acquisition] evidence is deemed limited not just when evidence is actually subject to manipulation, but rather is

ARGUMENT

I. THE RECORD DOES NOT PERMIT A FINDING THAT A "BLACK HAT" REVIEW WOULD HAVE ENDED THE X-RAY STRATEGY.

Defendants' assertion that the U.S. x-ray strategy would have fallen victim to a "black hat" financial review is not supported by credible evidence. At the hearing, Defendants' counsel asked Richard Steeves, Andrew McLean, Constance Baroudel, and Gavin Hill about the "black hat" process, and each gave a general description of his or her understanding of the process.[4] But the term "black hat" apparently is not part of the Synergy lexicon, as Defendants identified only two documents that even mention it, both from early 2013, and neither relating to x-ray.[5] In fact, a search of Synergy's nearly 2.3 million documents produced in this matter reveals only three substantive mentions of "black hat."[6] It is not the FTC's position that the business plan would never face further evaluation following the SEB meeting; indeed, documents show that Synergy planned to finalize the investment case at a November 2014 strategy session, a discussion that did not occur because of the proposed Steris acquisition.[7] But Defendants do not

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deemed of limited value whenever such evidence *could arguably* be subject to manipulation."); *FTC v. ProMedica Health Sys., Inc.*, No. 3:11 CV 47, 2011 WL 1219281 at *58 (N.D. Ohio Mar. 29, 2011) (quoting *Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1384 (7th Cir. 1986)) ("'[P]ost-acquisition evidence that is subject to manipulation by the party seeking to use it is entitled to little or no weight.'"). In *FTC v. Whole Foods Market Inc.*, evidence of pricing after the proposed merger was announced was deemed "all-but-meaningless," as Whole Foods had "every incentive to eliminate any price differences that may have previously existed between its stores based on the presence of a nearby Wild Oats, not only to avoid antitrust liability, but also because the company was no longer competing with Wild Oats." *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1047 (D.C. Cir. 2008) (Tatel, J., concurring in judgment).

[4] Steeves (Synergy) Hrg. Vol. 1 at 221:17-21; McLean (Synergy) Hrg. Vol. 2 at 412:14-413:8; Baroudel (Synergy) Hrg. Vol. 2 at 448:12-23; Hill (Synergy) Hrg. Vol. 3 at 678:18-679:23. Mr. Hill also described the purported "black hat" requirements in a declaration executed on February 25, 2015, that Synergy counsel submitted to the FTC staff. *See generally* JDX2858.

[5] JDX2268-002; JDX2869-004.

[6] JDX2869-004 (Finance Director's Report for February 2013); JDX2268-002 (Minutes of April 2013 plc Board Meeting); and PX01931 (March 21, 2013, email from Synergy's Tim Fowler, having read the February 2013 Finance Director's Report, asking [redacted]).

[7] JDX2260-001 (September 2014 COO Report stating, [redacted]; PX00583-001 (November 20, 2014, plc Board minutes explaining that, even though Mr. McLean had presented the "US AST Strategy Update" at the SEB strategy session earlier that week, "[i]t was acknowledged that the proposed acquisition by STERIS Corp. may have significant

offer a single contemporaneous business record showing that x-ray would be subjected to a "black hat" review—or a rigorous review by any other name—at some time in the future, or that any of the Synergy employees implementing the strategy had any inkling that x-ray would be subjected to any such review.

All that Defendants offer to support their assertion that the x-ray plan would have failed to meet Synergy's metrics in any such "black hat" review are general corporate guidelines and Monthly Finance Director Reports that they attached to the Hill Declaration.[8] But, again, they do not cite a single contemporaneous document that suggests that the business case must forecast at least a 15-percent, 10-year IRR to proceed. Instead, as Mr. Hill conceded, 4 of the 10 AST capital projects approved by Synergy between 2011 and 2014 forecasted 10-year IRRs below 15 percent.[9] Synergy uses both the 10-year IRR and IRR including terminal value as financial metrics in their business models, including the x-ray model.[10] The projected IRR including terminal value was 15.85 percent.[11] There is no contemporaneous evidence that Synergy would require the x-ray project to surpass a given level of 10-year IRR. Nor is there evidence that Synergy would require the project to surpass a given ROCE level.

Moreover, Mr. Hill, who claims he puts capital projects through a rigorous review, remained mostly silent as the SEB approved the x-ray strategy and the plc Board approved the IBA down payments in September 2014, even though Mr. Hill knew the details of the x-ray business plan.[12] Mr. Hill was complicit in representing to investors in November 2014 that Synergy had "signed an agreement with IBA for X-ray technology to be deployed in the United

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impact on the Group's strategy, and as such no recommendations were currently being made to the Board for their review or approval"). Synergy understood that the "New Steris" board must approve any capital expenditure. PX00791 (Hill (Synergy) Dep. at 261:15-21); *see also* PX00775 (Rosebrough (Steris) Dep. 91:16-92:11).

[8] JDX2859; JDX2864-011; JDX2865-008; JDX2866-010; JDX2867-011; JDX2868-009.

[9] Hill (Synergy) Hrg. Vol. 3 at 740:3-7.

[10] PX00275-035.

[11] PX00275-035.

[12] *See* PX00574-010; PX00655-041–048.

States, supplemented by our in-house knowledge and expertise."[13]

Finally, Mr. Hill testified at the hearing that, because Synergy receives more capital expenditure requests than it can fund in a given year, sometimes he has to tell his colleagues not to bother wasting their time on certain projects.[14] Although he testified that the x-ray business case was "woeful,"[15] he also conceded that he did not put a stop to Synergy's expenditures to implement the strategy, including (1) bringing 21 employees, many from Europe, to Tampa for a three-day Project Endurance kick-off meeting; (2) pursuing site selections and economic incentives in Ohio, Indiana, and Texas over a six-month period; (3) traveling to meet with potential customers; and (4) working out details of the purchase agreement with IBA.[16] Instead, as a member of the plc Board, Mr. Hill agreed to fund down payments for the x-ray equipment for the United States.[17] It begs credulity that Mr. Hill would not have urged these efforts to stop if he truly believed the x-ray case to be "woeful."

II. THE REAL-TIME WORDS AND ACTIONS OF THE EXECUTIVES CONFIRM THAT SYNERGY PROBABLY WOULD HAVE ENTERED THE UNITED STATES WITH X-RAY.

A. Synergy began implementing the entry plan after September 2014 board approvals.

Defendants assert that the presentation of the x-ray business plan to the SEB in September 2014 was a "progress update" and that the model "fell far short" of what would be required to obtain final approvals within the company.[18] This characterization does not square with contemporaneous business records. First, immediately following the SEB meeting,

[13] PX00580-004; Hill (Synergy) Hrg. Vol. 3 at 763:10-21; Plaintiff Federal Trade Commission's Post-Hearing Brief, Doc. No. 78 ("Pl.'s Br."), at 13 n.109.
[14] Hill (Synergy) Hrg. Vol. 3 at 761:24-762:6.
[15] Hill (Synergy) Hrg. Vol. 3 at 762:7-9.
[16] *See* Hill (Synergy) Hrg. Vol. 3 at 762:10-22.
[17] PX00574-010.
[18] Defs.' Br. at 5.

participants in that meeting—Mr. McLean and Gaet Tyranski—described the SEB's action as an approval to build the first two sites:

- "Most importantly, our x-ray strategy was approved this week during our Board meeting. We are going to completely transform how irradiation sterilization is done in the US and we have a compelling value proposition to support that, hence our Board having the confidence to make a very large capital investment to underpin a new nation-wide network."[19]
- "Went well. Approved. $40M investment."[20]
- "As you all know by now, the X-ray Strategy was approved by the SEB and we are now in implementation phase 1 and 2 – market development, R&D and build-out of 2 facilities."[21]

As a member of the SEB, Mr. McLean heard whatever criticism of the strategy may have occurred at the September SEB meeting, and had made it clear to the SEB at least twice before that customer commitments were unlikely to underpin the first facilities.[22] Likewise, Mr. Tyranski presented the x-ray business plan to the SEB, received positive feedback from Dr. Steeves and Adrian Coward,[23] both of whom sit on both the SEB and the plc Board, and subsequently led the Project Endurance team's implementation of the entry plan.[24] That these two principals considered the x-ray implementation plan to be approved by the SEB cannot be reconciled with the after-the-fact testimony that the SEB approved the strategy merely to give the x-ray team time to prepare a better business plan.

Second, the "feedback" from the SEB that the team aim to cut CAPEX by $1.5 million per facility, as reflected in McLean emails and the Project Endurance meeting slides, does not support Defendants' assertion that the SEB sent the team back to the drawing board because the

[19] PX-00922-001.
[20] PX-00347-001.
[21] PX-00400-001.
[22] *See* Pl.'s Br. at 5 n.35.
[23] Dr. Steeves said, "I just wanted to let you know that your presentation was very good yesterday. . . . Let's fine tune the capex for the expansion plans and regroup at the end of the month." PX01294-001. Dr. Coward said, "[w]ell done and keep up the good work," and "I know we can be a challenging Board at times (if not always!) so this goes to show how well you did in helping us to get to the right outcome." PX00272-001.
[24] Tyranski (Synergy) Hrg. Vol. 2 at 511:17-512:1, 521:6-23, 522:12-24; McLean (Synergy) Hrg. Vol. 2 at 293:22-294:2.

"present model fell far short of what would be needed. . . ."[25] Instead, the reactions to the feedback indicate that CAPEX reductions were never a gating item. Implementation continued, and soon there was no longer a mention of lowering CAPEX at all.[26] The contemporaneous record leaves no doubt that, following the September 2014 SEB meeting, the Project Endurance team understood it was to implement Phase I and Phase II of the x-ray strategy.[27]

B. The evidence does not support Defendants' assertion that the SEB found the x-ray financial model to be deficient.

Defendants point to Dr. Steeves's email to Mr. McLean following the September SEB meeting to support their assertion that the financial model "fell far short of what would be needed to obtain sign-off from the SEB."[28] In his response, however, Mr. McLean makes clear that the "numbers [in the U.S. x-ray model] were bolted down, however there were elements in the model that were highly conservative. I am hoping we do not misinterpret a conservative business case with not being on top of the numbers."[29] Mr. McLean's response shows that he believed that Dr. Steeves's criticism about financial work presented at the September SEB meeting related primarily to projects other than the U.S. x-ray plan. Specifically, Mr. McLean acknowledged that he was "quite embarrassed by the Tullamore case," a separate project presented at the September SEB meeting.[30]

Had the x-ray business model been as "poor" as Defendants say, there would have been expressions of concern about the future of the strategy immediately following the presentation to the SEB, particularly when the down payment request was made of the plc Board the next day. Instead, the plc Board minutes reveal that Dr. Steeves reported:

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[25] Defs.' Br. at 5.
[26] *See* Tyranski (Synergy) Hrg. Vol. 3 at 636:25-637:17, 633:3-634:10.
[27] *See* PX01794; PX01410-013; McLean (Synergy) Hrg. Vol. 2 at 327:10-328:11; PX00897-002; PX00194-005; Tyranski (Synergy) Hrg. Vol. 2 at 526:17-527:2.
[28] Defs.' Br. at 5.
[29] PX00215-001.
[30] McLean (Synergy) Hrg. Vol. 2 at 325:16-326:17.

- "AMc is working on entering in to an exclusivity agreement with IBA to ensure that Synergy was the only outsourced sterilisation provider they would supply X-ray equipment to in the US."[31]

- ". . . J&J had recently obtained the first regulatory approval for X-ray sterilisation of a Class III medical device, and . . . with the Cobalt costs likely to increase while electricity costs were falling it was likely that X-ray would be preferred to Cobalt sterilisation in any event."[32]

Dr. Coward, who participated in the x-ray discussion at the SEB meeting, reported at the plc Board meeting:

- "[He] considered it unlikely that if the proposed deal with [Steris] did not proceed there would be a decision to back away from X-ray for North America, given that it would be very difficult to provide gamma sterilisation in North America."[33]

Mr. Hill, who participated in the x-ray discussion at the SEB meeting, was silent about x-ray at the plc Board meeting.

Moreover, if the concerns now identified by the Synergy witnesses truly existed at the time, one would expect them to be revealed in the subsequent monthly reports. Instead, monthly reports following the September board meetings state:

- "The FDA have approved J&J Surgicel product for sterilization via x-ray. This is our first Class III medical device and represents a significant milestone in the development of our X-ray service offering. . . . X-Ray Americas cross-functional Core Team kickoff meeting held. The core team is working to solidify quotes for the main elements of the proposal for the upcoming SEB meeting. Two sites are being finalized and negotiated, the IBA agreement is close to finalization and more customer LOIs and product testing agreements are being aggressively pursued."[34]

- [redacted]

[31] PX00574-002.
[32] PX00574-010.
[33] PX00574-010.
[34] PX00897-002 (Mr. McLean's FY15 P6 AST & Laboratories Monthly Management Report for September 2014).
[35] PX00110-001 (Dr. Coward's COO Report for November 2014).

C. The proffered IBA documents do not support the assertion that the availability of adequate equipment became increasingly uncertain.

Defendants now assert Synergy faced increasing uncertainty in IBA's ability to configure equipment to meet Synergy's needs. They cite an October 13, 2014, email string between IBA and Synergy for the proposition that "IBA started hedging its assurances, and mentioned a larger and more expensive machine, the TT1000."[36] But the email shows that Synergy, not IBA, initiated the discussion of a larger machine and asked for a quote, and IBA responded seeking clarification of the requirements so that it could determine how best to meet its client's needs.[37]

There is no doubt that the two teams worked together to determine the optimal configuration and Synergy was pressing on price.[38] But it also is undisputed that two weeks after the October 13 email string highlighted by Defendants, Synergy executed the exclusivity arrangement that it announced to investors on November 4.[39] Thereafter, IBA and Synergy continued to work on the configuration as well as the details of a formal equipment purchase agreement.[40] The teams reached agreement on a configuration, and Mr. Tyranski directed that the x-ray business plan be updated accordingly.[41] Less than three weeks before Mr. Tyranski "killed" x-ray for the United States, he set a time frame to conclude remaining work necessary for the purchase agreement, and he advised IBA that Synergy would need another three-month extension on the exclusivity arrangement pending the close of the Steris transaction.[42]

Defendants also point out that IBA characterized the work on the TT1000 as "a research and development project."[43] But they fail to disclose that the same document, IBA's 2014-2018

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[36] Defs.' Br. at 12 (citing JDX1978-001).
[37] JDX1978-007.
[38] JDX1978-001–007.
[39] *See* McLean (Synergy) Hrg. Vol. 2 at 331:18-25.
[40] PX00237-001.
[41] *See* Pl.'s Br. at 12; PX01266-001-004; Tyranski (Synergy) Hrg. Vol. 3 at 565:6-13, 566:5-14.
[42] PX01316-001–002.
[43] Defs.' Br. at 13 (citing JDX1042-029).

Strategic Business Plan, budgets the sales to Synergy [redacted].[44] Even Mr. Tyranski, in response to a question from the Court, conceded that, as of February 2015, it was probable that IBA ultimately would deliver what Synergy needed.[45]

D. It is likely that customers would use x-ray in the United States but for the Steris transaction.

Defendants now assert that, throughout 2014, Synergy "solicited customer interest," but "none had committed."[46] But the record is clear that Synergy did not seek commitments, and instead actively cultivated customers to test their products with x-ray at Däniken as a first step toward regulatory approvals.[47] Customers were testing products in January and February 2015,[48] and others were planning to test in March and April 2015.[49] Defendants also assert that the FTC "cherry-picked" Johnson & Johnson and Zimmer Biomet to testify at the hearing, but they omit the fact that both expressed current interest in x-ray and neither had been offered a concrete take-or-pay contract proposal.[50] Customers have been, and continue to be, interested in x-ray in the United States.[51] These customers represent some of the largest medical device manufacturers in the world. The FTC anticipates that more customers will testify at the full trial on the merits.

Despite Defendants' assertion that neither J&J nor Zimmer "came close to committing to U.S. x-ray,"[52] the testimony at the hearing was clear that significant customer interest in U.S. x-

[44] JDX1042-027. IBA's Jean-Louis Bol testified that [redacted] Bol (IBA) Dep. at 242:16-244:6.
[45] Tyranski (Synergy) Hrg. Vol. 3 at 577:6-15.
[46] Defs.' Br. at 9.
[47] *See* Pl.'s Br. at 9-11.
[48] *See* Pl.'s Br. at 10, 10 n.82, 11, 11 n.83.
[49] *See* PX00618 (Kook (Baxter) Decl. ¶¶ 8-9); PX00615 (Wilson (CTS) Decl. ¶ 23).
[50] Defs.' Br. at 10.
[51] *See* PX00601 (Hansen (J&J) Decl. ¶ 19); PX00605 (Spang (Haemonetics) Decl. ¶ 16); PX00606 (Snyder (DCIDS) Decl. ¶ 13); PX00610 (Silor (Zimmer) Decl. ¶¶ 16-18); PX00611 (Elliott (Amniolife) Decl. ¶ 17); PX00625 (Zheng (Thermo Fisher) Decl. ¶ 22); PX00615 (Wilson (CTS) Decl. ¶ 23); PX00616 (Thome (St. Jude) Decl. ¶ 12); PX00617 (Irwin (Covidien) Decl. ¶ 15); PX00618 (Kook (Baxter) Decl. ¶¶ 8-9).
[52] Defs.' Br. at 10.

ray remains. Synergy faced no deadline for gaining customer conversions to x-ray.[53] To this day, the company advertises its x-ray services on the U.S. version of its website.[54] Zimmer's products are already at the Däniken facility, to be tested as early as this month.[55] Now that it has received regulatory approvals, J&J intends to use x-ray for Surgicel, and will begin the process of converting additional products.[56] At the hearing, Mr. McLean testified that, once J&J converted to x-ray, others would follow.[57] This is precisely what Synergy told investors in November 2014, when it announced "the first FDA approval of a Class III medical device was achieved by one of our major global customer partners, paving the way for further conversions."[58] Similarly, back in 2013, Dr. Steeves predicted that J&J "will be our first major breakthrough in the medtech world. Once that happens then it will be easy going."[59] But for the FTC investigation, Synergy would be promoting x-ray for the United States, preparing to advertise the anticipated conversion of J&J's Surgicel to x-ray, and nearing conversions of other products for other customers, all in anticipation of entry as early as 2016.

CONCLUSION

For the foregoing reasons, the FTC respectfully requests that this Court grant the preliminary injunction.

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[53] McLean (Synergy) Hrg. Vol. 2 at 353:11-354:12.

[54] *See* Synergy Website, "X-Ray Processing," http://www.synergyhealthplc.com/en/applied-sterilisation-technologies/x-ray?region=348&country=US (last visited Sept. 3, 2015). Däniken continues to build business. Defendants' assertion that Däniken's x-ray capacity utilization barely increased, from 22 percent when it was acquired to 25-30 percent in 2015, is inaccurate. Däniken processed only 4,440 x-ray pallets in 2011, the year prior to its March 2012 purchase. PX00423-022. By March of 2015, it was processing roughly 20,000 pallets per year, an increase of more than 300 percent. PX00714 (Hartmann (Synergy) IH at 49:1-16). Given an x-ray capacity of 80,000 pallets per year, Däniken's x-ray capacity utilization actually increased from less than 6 percent at time of purchase to about 25 percent in 2015. *Id.* at 49:10-18. This is consistent with Synergy's representation to investors in November 2014 that x-ray is AST's fastest growing technology. PX00580-004.

[55] Silor (Zimmer) Hrg. Vol. 1 at 119:14-120:6; 146:8-147:4.

[56] Pl.'s Br. at 11, 11 n.90.

[57] McLean (Synergy) Hrg. Vol. 2 at 338:24-339:6.

[58] PX00580-004.

[59] PX00095-002.

Date: September 4, 2015

Respectfully submitted,

/s/ Tara L. Reinhart

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CERTIFICATE OF SERVICE

I hereby **CERTIFY** that on September 4, 2015, a copy of the foregoing document, Plaintiff Federal Trade Commission's [Redacted] Post-Hearing Response Brief, was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system ("CM/ECF") to all parties indicated on the electronic filing receipt. Parties may access this filing via the Court's CM/ECF system.

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